K082759

510(k) Summary of Safety and Effectiveness

APR 10 2009

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number:

Date of Summary Preparation: September 18, 2008

Manufacturer:
Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:
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Device Name:
EliA™ CENP Immunoassay
EliA™ U1RNP Immunoassay
EliA™ Sm Immunoassay
EliA™ Ro Immunoassay
EliA™ La Immunoassay

Common Name: Antinuclear antibody immunological test system and Control

Classification

Product Name	Product Code	Class	CFR
EliA™ CENP	LJM	II	866.5100
EliA™ U1RNP	LJM	II	866.5100
EliA™ Sm	LJM	II	866.5100
EliA™ Ro	LJM	II	866.5100
EliA™ La	LJM	II	866.5100

Substantial Equivalence to

Varelisa CENP Antibodies	K944171
Varelisa U1RNP Antibodies	K993589
Varelisa Sm Antibodies	K000312
Quanta Lite SS-A ELISA	K922830
Varelisa SS-B/La Antibodies	K944168

Intended Use Statements of the New Devices

1) EliA™ CENP is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to CENP in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of scleroderma (CREST Syndrome) in conjunction with other laboratory and clinical findings. EliA™ CENP uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

2) EliA™ U1RNP is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to U1RNP in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of mixed connective tissue disease (MCTD) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ U1RNP uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

3) EliA™ Sm is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Sm in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ Sm uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

4) EliA™ Ro is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ Ro uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

5) EliA™ La is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to La in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ La uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

ImmunoCAP® 100/ImmunoCAP® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Devices

The new devices belong to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments ImmunoCAP 100 and ImmunoCAP 250. The conjugate for the EliA IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate. The total IgG calibration is based on a set of six WHO-standardized IgG Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method specific and general reagents that are packaged as separate units.

Test Principle of the New Devices

The EliA Wells are coated with the following antigens:

Test	Antigen coated to the wells:
EliA CENP	human recombinant centromere protein B
EliA U1RNP	human recombinant RNP (RNP 70 kDa, A, C) protein
EliA Sm	native Sm proteins purified from bovine tissue
EliA Ro	human recombinant SS-A/Ro (60 kDa, 52 kDa) protein
EliA La	human recombinant SS-B/La protein

If present in the patient's specimen, antibodies to the antigens mentioned above bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison

The new and the predicate devices both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of the following diseases:

Disease	Detection of antibodies to
scleroderma (CREST Syndrome)	CENP
mixed connective tissue disease (MCTD)	U1RNP
systemic lupus erythematosus (SLE)	Sm, U1RNP, Ro, La
Sjögren's syndrome	Ro, La

Laboratory equivalence

The comparability of predicate device and new device is supported by a data set including

- **results obtained within a comparison study between new and predicate devices**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 10 2009

Phadia US, Inc
c/o Mr. Martin R. Mann
Regulatory Affairs Manager
4169 Commercial Ave
Portage, Michigan 49002

Re: k082759
Trade/Device Name: EliA™ CENP
EliA™ U1RNP
EliA™ Sm
EliA™ Ro
EliA™ La
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: II
Product Code: LJM
Dated: April 3, 2009
Received: April 6, 2009

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

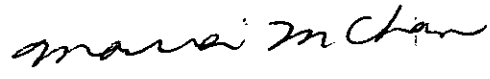
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K082759

Device Name: **EliA Sm Well**

Indication For Use:

EliA™ Sm is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Sm in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ Sm uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082759

Indication for Use

510(k) Number (if known): K082759

Device Name: **EliA La Well**

Indication For Use:

EliA™ La is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to La in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ La uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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Evaluation and Safety

510(k) K082759

Indication for Use

510(k) Number (if known): K082759

Device Name: **EliA Ro Well**

Indication For Use:

EliA™ Ro is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ Ro uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

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510(k) K082759

Indication for Use

510(k) Number (if known): K082759

Device Name: **EliA U1RNP Well**

Indication For Use:

EliA™ U1RNP is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to U1RNP in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of mixed connective tissue disease (MCTD) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ U1RNP uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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510(k) K082759

Indication for Use

510(k) Number (if known): K082759

Device Name: **EliA CENP Well**

Indication For Use:

EliA™ CENP is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to CENP in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of scleroderma (CREST Syndrome) in conjunction with other laboratory and clinical findings. EliA™ CENP uses the EliA IgG method on the instruments ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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